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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Schneewind	Examiner:	M. Navarro
Serial No.	09/292,437	Group Art Unit:	1645
Filed:	April 15, 1999	Docket No.	510015-213
Title:	IDENTIFICATION OF SORTASE GENE		

CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper and its enclosures are being deposited in the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on December 4, 2000.

Joy Johnson

RESPONSE TO RESTRICTION REQUIREMENT

Honorable Assistant Commissioner for Patents
Washington, D.C. 20231

Gentlemen:

In response to the Restriction Requirement and objection to sequence listing dated October 4, 2000, please amend the application as follows:

In the Specification:

Please amend the specification by deleting pages 1-14 of the Sequence Listing submitted with the specification and substituting therefor pages 1-11 of the new Sequence Listing submitted with this Response.

I. THE RESTRICTION REQUIREMENT

Restriction to the invention of one of the following groups is required under 35 U.S.C. § 121 as follows:

Group I is claims 1-7, 26-29, and 49-54, drawn to a sortase-transamidase enzyme, classified in Class 435, subclass 183.

Group II is claims 8-25, drawn to nucleic acids encoding a sortase-transamidase enzyme, classified in Class 536, subclass 23.1.

Group III is claims 30-42, drawn to a method for screening a compound for anti-sortase-transamidase activity, classified in Class 435, subclass 7.1.

Group IV is claims 43-48, drawn to antibodies, classified in Class 530, subclass 387.1.

Group V is claims 55-61, drawn to a method for displaying a polypeptide on the surface of a Gram-positive bacterium, classified in Class 435, subclass 69.1.

Group VI is claims 62-65, drawn to a polypeptide displayed on the surface of a Gram-positive bacterium by covalent linkage, classified in Class 530, subclass 300.

Group VII is claim 66, drawn to a method for vaccination of an animal with a polypeptide, classified in Class 424, subclass 193.1.

Group VIII is claim 67, drawn to a method for vaccination of an animal with a covalent complex, classified in Class 424, subclass 193.1.

Group IX is claims 68-74, drawn to a method for screening for expression of a cloned polypeptide, classified in Class 435, subclass 6.

Group X is claims 75-78, drawn to a method for a diagnosis of a bacterial infection, classified in Class 435, subclass 7.4.

Group XI is claims 79-83, drawn to a conjugate comprising an antibiotic and a protein, classified in Class 530, subclass 350.

Group XII is claims 84-89, drawn to proteins having sortase-transamidase activity, classified in Class 435, subclass 183.

Group XIII is claims 90-97, drawn to DNA encoding the proteins of Group XII, classified in Class 536, subclass 23.1.

In the event that Group XII or XIII is elected, there is a further restriction to one sequence (i.e., one of SEQ ID NO: 4, 5, 6, 7. 8, 34, 35, or 36) for prosecution.

The inventions of Groups I and II were said to be distinct because they were said to be products with different structure and biological activities.

The invention of Group IV was said to be distinct from those of Inventions Groups I-III and V-XIII, because an antibody was stated to have an inherent affinity, avidity, and specificity that differed from those of simple proteins or DNA.

The invention of Group III was stated to be distinct from those of Groups I-II and IV-XIII, because the method was stated to require additional biological reagents and parameters for detection. Similarly, the invention of Group IV was stated to be distinct from those of Groups I-IV and VII-XIII for similar reasons. Analogously, the invention of Group IX and X were stated to be distinct from those of the other Groups for similar reasons.

The invention of Group VI was said to be distinct from those of Groups I-V and VII-XIII, because the invention of Group VI was stated to require the polypeptide to be displayed in a manner that is accessible to a ligand.

The invention of Group VII was stated to be related to the invention of Group I as product and process of use, but was said to be distinct because the polypeptide of Group I could be used in other methods.

The invention of Group VIII was stated to be distinct from those of Groups I-VII and IX-XIII, because it was stated to require vaccination with a covalent complex which has a separate biological activity and function.

The invention of Group XI was stated to be distinct from those of Groups I-X and XI-XIII, because it was stated that the conjugate of the antibody and the protein has a unique biological activity and function.

The invention of Group XII was stated to be distinct from those of Groups I-XI and XIII, as it was stated that they were all distinct proteins.

The invention of Group XIII was stated to be distinct from those of Groups I-XII, because they were stated to encode distinct proteins with distinct primary amino acid structures.

II. APPLICANT'S RESPONSE

Applicant hereby elects with traverse the invention of Group II, claims 8-25, drawn to nucleic acids encoding a sortase-transamidase enzyme, for prosecution on the merits.

The Restriction Requirement is respectfully traversed on the following grounds:

Firstly, the Examiner has not met the required burden for demonstrating the necessity for restriction. M.P.E.P. § 803 requires for restriction both: (1) that the inventions are independent or distinct as claimed and (2) that there would exist a "serious burden" on the Examiner if all of the claims were examined together in one application.

These requirements have not been met. Firstly, there is no demonstration that a "serious burden" on the Examiner would exist.

The subject matter of the inventions of the various groups is sufficiently interrelated that no serious burden on the Examiner would exist if all of the claims were examined on the merits. This is because the art involved, if relevant art exists, largely overlaps. For example, publications describing the properties of cloned genes or genetically engineered protein constructs invariably report both the sequence of the cloned gene and the sequence of the resulting protein expressed from an open reading frame (orf). Similarly, the sequence listing in this application and other applications and patents include both the nucleic acid sequence and the resulting protein sequence from an open reading frame. This encompasses the inventions of Groups I and II and requires that they be examined together.

Similarly, such publications also typically report both the sequence and the properties of such proteins, including their immunological properties. These publications also typically report the activity of these proteins, including the product of their enzymatic activity. This would encompass at least the inventions of Groups III (screening activity), V (peptide display), and VI (polypeptide displayed by covalent linkage).

These publications also frequently describe the antigenic and immunogenic properties of the proteins described therein, including the preparation of antibodies. This would encompass the subject matter of Group IV.

Therefore, a "serious burden" on the Examiner sufficient to require restriction does not exist, at least for the inventions of Groups I, II, III, IV, V, and VI.

Secondly, the subject matter of the inventions as claimed is not distinct, but rather is related. This is because all of these inventions are substantially related by the activity of the sortase-transamidase enzyme.

Applicant does not traverse the restriction requirement on the basis of lack of patentable distinctness. Rather, Applicant traverses the restriction requirement on the relatedness of the subject matter of the inventions of the various groups, notwithstanding the possible existence of patentable distinctness. The inventions are related because they all rely on the structure or activity of the sortase-transamidase enzyme. Applicant, who is presenting this information in a unitary manner in one patent application, should not be penalized by restriction when the subject matter of the inventions of these groups is so clearly related.

The comments made by the Examiner at pages 3-6 of the Restriction Requirement are not to the contrary. Notwithstanding the different properties of the proteins, nucleic acids, and methods of the inventions of these groups, they are still sufficiently related to avoid restriction. More significantly, the art required to search all of these groups is so closely related that there does not exist a "serious burden" on the Examiner if all of these inventions were searched and examined in a single application. The determination of the existence or non-existence of a "serious burden" should not be made according to arbitrary principles, but should reflect the actual state of the art.

Accordingly, the Restriction Requirement is respectfully traversed. The Examiner is therefore respectfully requested to either withdraw the Restriction Requirement and examine all of the claims on the merits, or, in the alternative, modify the Restriction Requirement and examine the inventions of Groups I-VI on the merits.

II. OTHER MATTERS RAISED IN THE RESTRICTION REQUIREMENT

The Sequence Listing was objected to as non-compliant with the requirements of 37 C.F.R. §§ 1.821-1.825

To address these concerns and assure compliance with the requirements of 37 C.F.R. §§ 1.821-1.825, a new Sequence Listing is being submitted in both computer-readable form and in the form of a substitute paper copy. The content of the paper and computer-readable

copies are the same. This substitute Sequence Listing introduces no new matter and merely corrects the errors noted. Accordingly, entry of the Sequence Listing is respectfully requested.

Respectfully submitted,

Dated: December 4, 2000

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